



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/675,147

09/30/2003

Gilbert R. Gonzales

SERE-06

5607

26875 7590 04/16/2007
WOOD, HERRON & EVANS, LLP
2700 CAREW TOWER
441 VINE STREET
CINCINNATI, OH 45202

EXAMINER

HUH, BENJAMIN

ART UNIT

PAPER NUMBER

3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
--	-----------	---------------

3 MONTHS

04/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/675,147

Applicant(s)

GONZALES, GILBERT R.

Examiner

Benjamin Huh

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/12/07 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The step of actually administering the medication to the patient. It is suggested that the applicant amend the claims to state "delivering medication through said tube and into said venous blood vessel of said patient".

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-24 & 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzales et al (US Patent No. 5846216) and further in view of Winchell et al (US Patent No. 5061243) or Brennan (US Patent No. 4941875). The Gonzales reference discloses an infusor system for administering medications in a body of a patient comprising a flexible, elongated delivery tube having opposite ends, one of said ends couplable to a supply of liquid medication, said supply being remote from a venous blood vessel; a delivery component, a pressure altering device, and the administration of the drug to the venous blood vessels, see col. 2 line 43 – col. 3 line 14 & col. 6 lines 15-27. Now, even though Gonzales does not disclose the administration of medication directly into the venous blood vessel attention is directed to Winchell or Brennan. The Winchell and Brennan references teach the use of a venous needle delivering medications; see Winchell claim 5, col. 3 lines 3-13, col.5 lines 55-58, and col. 10 line 67- col. 11 line 7 and Brennan col. 3 lines 33-40 & claims 1, 6, 9, & 11. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Gonzales with the teachings of Winchell or Brennan in order to provide a means for facilitating the piercing and entering of the blood vessel so that direct supply can be provided. Wherein the advantages of utilizing direct delivery via a needle/catheter rather than going through a membrane are well known in the art. The examiner would also like to note that since the claim is a device claim, the combination

of Gonzales in view of Winchell only need be fully capable of performing the functional limitations of the claims.

With respect to claims 3-4, wherein the device of Gonzales in view of Winchell would be fully capable of being placed in confronting relationship with a venous blood vessel of the superficial or sacral venous system of the human body due to it's size, shape, and ability to work in the environment.

With respect to claims 5-7, the Gonzales reference discloses a liquid medication and a valve allowing flow, see claims 5 & 6 and col. 4 lines 12-19.

With respect to claims 9-12, the Gonzales reference discloses an increase in intra-abdominal pressure utilizing a binder or restraint, see col. 2 line 43 – col. 3 line 14 & col. 6 lines 15-27.

With respect to claims 13, 23, & 25, wherein the device of Gonzales discloses a method of administering medications to a patient via a pudic vein. Now even though Gonzales in view of Winchell or Brennan does not explicitly place the delivery component in confronting relationship with a pudic vein, Winchell and Brennan both disclose placing the needle into the desired vein. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to place the needle of Winchell or Breannan into a pudic vein and directly into the bloodstream which is where the drug is taught to go by Gonzales. Wherein the advantages of utilizing direct delivery via a needle/catheter rather than going through a membrane are well known in the art.

With respect to claims 16-17, the Gonzales reference discloses the use of an IV bag with a connecting pump, see col. 4 lines 12-19.

With respect to claims 18-21, the Gonzales reference discloses an increase in intra-abdominal pressure utilizing a binder or restraint, see col. 2 line 43 – col. 3 line 14 & col. 6 lines 15-27.

With respect to claim 22, the Gonzales reference discloses a liquid medication and a valve allowing flow, see claims 5 & 6 and col. 4 lines 12-19.

With respect to claims 24-26, the Gonzales reference teaches delivering liquid medication to a spinal region of the body, see col. 12 line 28 – col. 13 line 28.

Claims 25 & 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzales et al (US Patent No. 5846216) and further in view of Winchell et al (US Patent No. 5061243) or Brennan (US Patent No. 4941875) as applied above and further in view of Lynn et al (US Patent No. 5549569). Now even though Gonzales does not explicitly disclose the sampling or aspirating of venous blood attention is directed to Lynn. The Lynn reference teaches sampling or aspirating of venous blood. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the method of Gonzales with the teachings of Lynn in order to obtain blood samples for further testing.

Response to Amendment

The declaration filed on 2/12/07 under 37 CFR 1.131 has been considered but is ineffective to overcome the Gonzalez reference in view of the new rejection.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

